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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/586,755

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EXAMINER

IPPOLITO RAUSCH, NICOLE

ART UNIT

PAPER NUMBER

2881

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/586,755	Applicant(s) CASALE ET AL.	
	Examiner NICOLE IPPOLITO RAUSCH	Art Unit 2881	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,11,16 and 18-22 is/are rejected.
- 7) ☒ Claim(s) 3,8-10,12-15 and 17 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 July 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/21/2007</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Drawings

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings look as though they are either (i) hand-drawn or (ii) are of general poor quality, as they appear to have been copied and pasted from perhaps a circuit diagram, in which resolution was lost. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance. Furthermore, the drawings are not discussed at all with respect to the claims themselves. This should be rectified in the "Detailed Disclosure".

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.

Art Unit: 2881

- (1) Field of the Invention.
- (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

2. The disclosure is objected to because of the following informalities: the repeated use of .sup.00 Mo/.sup.99m, which is clearly intended to have post and/or super-scripts. This error occurs many, many times throughout the specification. Furthermore, page 2 line 1 "sensing" should be "sensing", in paragraph 0004 the Examiner fails to comprehend what is meant by "made from by neutrons little activable materials serves first as reactor irradiation ampoule", in paragraph 0006 "generator has a matrix" should be "generator that has a matrix", in paragraph 0010 "generator at a any given time" does not require the "a", in paragraph 0025 the Examiner is unclear why "Nuclear Medicine" is capitalized, and also "userregarding" should be "user regarding", in paragraph 0031 "radionucledicipurity" should be "radionucleidic purity" and "Sterility" need not be capitalized, and in paragraph 0049 the Examiner does not know what is meant by "if the resitent does not return to the infinite". Furthermore, these are only the grammatical and typing errors which were immediately apparent to the Examiner. It is strongly recommended that a thorough editorial check-through of both the specification and claims be performed.

Appropriate correction is required.

Claim Objections

3. Claim 20 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer back in the alternative only. See MPEP § 608.01(n). Accordingly, the claim 20 has not been further treated on the merits.

However, please do note that the examiner was provided with three (3) sets of claims all submitted on 7/20/2006. Therefore, the examiner is considering the claims which were subject to a preliminary amendment which rectifies claim 20. However, as the case file currently appears, it is unclear if the examiner should consider the "preliminary amended" claims or the claims which read "****for U.S. filing****".

4. Claim 11 is objected to because of the following informalities: the use of "and" when selecting within a group (see last line). The Examiner believes this was meant to be "or". Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically in this instance, "nuclear quality" is undefined by both the specification and claims. The Examiner will infer it to mean "level of radioactivity achieved/wanted" for the purposes of examination; however, clarification as to what is meant by this term is required.

Art Unit: 2881

7. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a geometry that allows for metal tubing to have an IN and OUT. This borders on a lack of antecedent basis problem-for there is not given any basis for the existence of the claimed tubing. Furthermore, the only mention on the generator is made in the preamble, which is not given patentable weight. Therefore, there lacks basis for the generator as well-including what exactly this generator is meant to be creating.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 2881

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-2, 4, 6-7, 11, 16 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whiting et al. (U.S. Patent Number 6157036, from hereinafter "Whiting") in view of Egorov et al. (U.S. Patent Number 6972414, from hereinafter "Egorov") in further view of Stoll et al. (U.S. Patent Number 6267717, from hereinafter "Stoll").

11. In regards to claim 1, Whiting teaches a radioisotope generator (FIG. 2, column 8 provides a synopsis of the system). Whiting likewise teaches an electronic sensor of elution as well as an eluted activity measurement sensor (column 10 lines 34-51).

Regarding claim 1, Whiting fails to teach a means for measuring nuclear quality of the eluted radioisotope, as well as an electronic memory with information for a user, a communication interface and user interface software.

Egorov does teach an electronic memory with information for a user, a communication interface and user interface software (columns 5-6, lines 58-12).

In view of the teachings of Egorov it would have been obvious to one of ordinary skill in the art at the time the invention was made to include an electronic memory with information for a user, a communication interface and user interface software.

Computers are widespread and, for an application which requires any degree of sensitivity, are absolutely essential. To allow for fine-tuning of the system as well as increased controller and faster feedback of information, the inclusion of such devices would have been obvious.

Art Unit: 2881

Regarding claim 1, Whiting as modified by Egorov fails to teach a means for measuring nuclear quality of the eluted radioisotope.

Stoll teaches a means for measuring nuclear quality of the eluted radioisotope (abstract, column 11 lines 15-48).

In view of the teaching of Stoll it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a means for measuring nuclear quality of the eluted radioisotope. As many of these generated isotopes go on to be used in medical application (as in the case of Stoll), the actual level of radioactivity achieved is a crucial but if knowledge to prevent possible over or under-dosing of the patient, and in general to protect those who must work around said isotope.

12. In regards to claim 2, Whiting does teach that the radioisotope generator is Mo-99/TC-99 (column 1 lines 25-30, and listed within the references. Clearly this is a well-known process).

13. In regards to claim 4, Whiting as modified by Egorov and Stoll as discussed above fails to teach that the eluted activity sensor is comprised of a Geiger Muller tube, a micro-ionization chamber or a solid state detector.

However, Stoll does teach that the eluted activity sensor is comprised of a Geiger Muller tube (see, i.e., column 3 lines 30-41).

In view of this further teaching of Stoll it would have been obvious to one of ordinary skill in the art at the time the invention was made that the eluted activity sensor is comprised of a Geiger Muller tube. Such systems are well known in the art, have existed for decades, and are quite accurate. It would have been obvious to utilize such

Art Unit: 2881

a well-known system as they are simple to operate, as well as comparatively inexpensive.

14. In regards to claim 6, although Whiting as modified by Egorov and Stoll as discussed above fails to explicitly teach that the communication interface uses one of an RS232, USB or parallel port, it would have been obvious. Particularly in the instances of USB and parallel ports, such devices are well known in the art for computer-to-device communication. As these ports are standard on most PC's (i.e. included), it would have been obvious to use the communication interface that requires no additional hardware ports.

15. In regards to claims 7, 16 and 19, Whiting as modified by Egorov and Stoll as discussed above do not teach that the means for measuring is comprised of a radioactivity sensor protected by a 3mm lead shield.

However, Stoll does teach that the means for measuring is comprised of a radioactivity sensor protected by a 3mm lead shield (column 3 teaches a Geiger Muller tube, used for measuring the radioactivity, while, i.e., FIG. 14, column 15 discusses a shield. Though no thickness is discussed, it would have been obvious to use the thinnest shield that is practical, as lead is quite heavy).

In view of this further teaching of Stoll it would have been obvious to one of ordinary skill in the art at the time the invention was made that the means for measuring is comprised of a radioactivity sensor protected by a 3mm lead shield. As discussed above, radioactivity sensors are the cheap, simple, economical choice for radiation detection. Furthermore, shielding is generally necessary to protect both people and

Art Unit: 2881

devices from over-exposure. In general, lead is an obvious choice due to its high level of efficacy. It would be obvious though to use the thinnest shield possible, as lead is both heavy and bulky, and require valuable space within the laboratory/industrial setting.

16. In regards to claim 11, the same arguments apply as for claim 1. However, Whiting as modified by Egorov and Stoll fail to teach using high-frequency conductometry, impedanceceometry, electrical capacitometry, emitted radiation detection, and magnetic-hydrodynamic principles.

However, Stoll does teach using emitted radiation detection (see, i.e., column 3 lines 30-41).

In view of this further teaching of Stoll it would have been obvious to one of ordinary skill in the art at the time the invention was made to measure the emitted radiation. Such systems are well known in the art, have existed for decades, and are quite accurate. It would have been obvious to utilize such a well-known system as they are simple to operate, as well as comparatively inexpensive.

17. In regards to claim 20, although Whiting as modified by Egorov and Stoll as discussed above fails to explicitly teach that the communication interface uses one of an RS232, USB or parallel port, it would have been obvious. Particularly in the instances of USB and parallel ports, such devices are well known in the art for computer-to-device communication. As these ports are standard on most PC's (i.e. included), it would have been obvious to use the communication interface that requires no additional hardware ports.

Art Unit: 2881

18. In regards to claim 22, although Whiting as modified by Egorov and Stoll as discussed above fails to explicitly teach that the software is able to process and log all data introduced from the generator, it would have been obvious. Both Egorov and Stoll teach computers. In general, the data would in fact be saved (i.e. logged) for later use, so that at a later date (i.e. in medical applications as discussed by Stoll) this information may be retrieved and checked so that, i.e., the patient pay be kept safe from over or under exposure.

19. Claims 5 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whiting as modified by Egorov and Stoll as applied to claim 1 above, and further in view of Whittacre et al. (U.S. Patent Application Publication Number 20030139640, from hereinafter "Whittacre"). The teachings of Whiting, Egorov and Stoll have been discussed above.

20. In regards to claim 5, Whiting as modified by Egorov and Stoll fails to teach that the electronic memory with information is comprised of lot number, generator number, activity, calibration date and expiration date.

Whittacre teaches storing various dates that relate to radioisotopes (paragraphs 0178 and 0195).

In view of the teaching of Whittacre it would have been obvious to one of ordinary skill in the art at the time the invention was made that the electronic memory with information is comprised of lot number, generator number, activity, calibration date and expiration date. These are all crucial values that lend themselves to the safety of the

Art Unit: 2881

radioisotope before it is used, and therefore, having such data available would have been obvious.

21. In regards to claim 21, Whiting as modified by Egorov, Stoll and Whittacre as discussed above fails to explicitly teach that the electronic memory is comprised of non-volatile memory and that, upon connecting to a PC, transferring information stored by the manufacturer to a particular generator. However, it would have been obvious. Non-volatile memory (i.e., EPROM) is well known in the art for storing information for short periods of time where large amounts of data must be transferred repeatedly. The use of non-volatile memory techniques are so well known that it would have been completely obvious to use such techniques in an instance such as this, as it was for reasons as presented in the instant application that the techniques were invented in the first place.

Allowable Subject Matter

22. Claims 3, 8-10, 12-15 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

23. The following is a statement of reasons for the indication of allowable subject matter: Although the art listed above in the 103(a) rejections appears to be the most pertinent prior art available, the art above fails to cover any particular specifics of the sensing, and in particular does not cover the concepts encompassed in the objected claims-specifically utilizing changes in photon intensity, resistance, impedance, or dielectric capacity to determine changes in the elution chamber.

Conclusion

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE IPPOLITO RAUSCH whose telephone number is (571)270-7449. The examiner can normally be reached on Monday through Thursday 6:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Kim can be reached on (571)272-2293. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. I./
Examiner, Art Unit 2881

/ROBERT KIM/

Application/Control Number: 10/586,755

Page 13

Art Unit: 2881

Supervisory Patent Examiner, Art Unit 2881